

UNITED STATES DISTRICT COURT

for the
District of Delaware

Par Pharmaceutical, Inc. et al.

Plaintiff

v.

Zydus Pharmaceuticals (USA) Inc. et al.

Defendant

Civil Action No. 1:23-cv-00866-JLH-LDH

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS
OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTIONTo: Medichem, S.A. c/o Medichem, LLC
80 Broad Streete, Suite 2103, New York, NY 10004

(Name of person to whom this subpoena is directed)

☒ **Production:** **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Schedule A

Place: Locke Lord LLP
Brookfield Place 200, Versey Street, 20th Floor,
New York, NY 10281-2101

Date and Time:

03/18/2024 9:00 am

☐ **Inspection of Premises:** **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:

Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 02/16/2024

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/ Jacob C. Britz

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party) Zydus Pharmaceuticals (USA) Inc. et al., who issues or requests this subpoena, are:

Jacob C. Britz, 111 South Wacker Drive, Suite 4100, Chicago, IL 60606, jacob.britz@lockelord.com, 312-443-0632

Notice to the person who issues or requests this subpoena

A notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

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PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____
on *(date)* _____.

☐ I served the subpoena by delivering a copy to the named person as follows: _____

_____ on *(date)* _____; or

☐ I returned the subpoena unexecuted because: _____
_____.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)**(c) Place of Compliance.**

(1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
 - (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

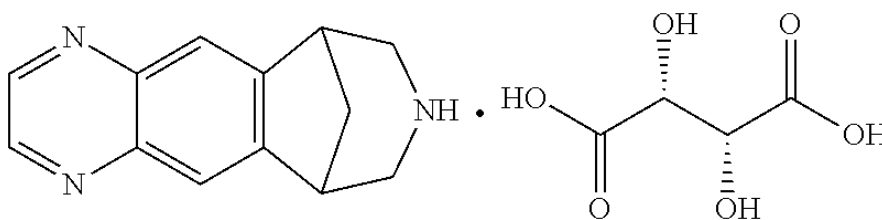
(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

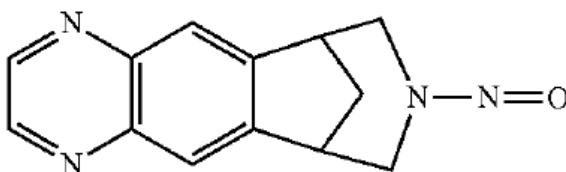
SCHEDULE A

DEFINITIONS

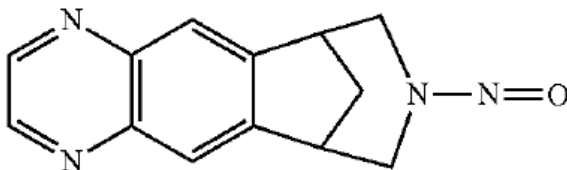
1. “Medichem’s DMF” means Drug Master File No. 023728.
2. “FDA” means the United States Food and Drug Administration.
3. “Varenicline Tartrate” means any substance containing the chemical compound having the name of 7,8,9,10-tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]benzazepine tartrate and having the structural formula represented by the following:



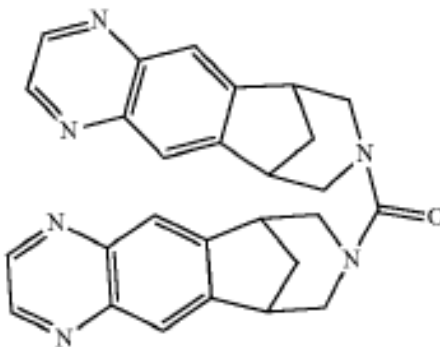
4. “Nitrosamine Impurity” or “Nitrosamine Impurities” mean any N-nitrosamine substance, including but not limited to the chemical compound having the name of 7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino[2,3-h][3]benzazepine and having the structural formula represented by the following:



5. “N-Nitroso-Varenicline” means the chemical compound having the name of 7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino[2,3-h][3]benzazepine and having the structural formula represented by the following:



6. The “Diamide” impurity means the chemical compound having the name Bix(7,8,9,10-tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]-benzazepine)-amide and having the structural formula represented by the following:



7. “You” or “Your” or “Medichem” refers to Medichem, S.A., including your affiliates, subsidiaries, employees, and/or any other Persons or entities purporting to act on your behalf and/or under your control.

8. “Zydus” means Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited, and all of its affiliates, subsidiaries, employees, and/or any other persons or entities purporting to act on its behalf and/or under its control.

INSTRUCTIONS

1. If You withhold information on the grounds of privilege (including work product immunity), You must identify the nature of the privilege that is being claimed and must provide: (a) the type of Document, e.g., letter or memorandum; (b) the general subject matter of the Document; (c) the date of the Document; (d) the Bates range of the Document; and (e) such other

information as is sufficient to identify the Document, including, where appropriate, the author of the Document, the addressees of the Document, and any other recipients shown in the Document, and, where not apparent, the relationship of the author, addressees, and recipients to each other. Any privilege log or list is to be produced in an Excel spreadsheet or other format capable of electronic sorting.

2. Pursuant to Rule 34(b) of the Federal Rules of Civil Procedure, all electronically stored information should be produced in image or native format and all should be given a discrete production number. All files, regardless of whether they are produced in image format or as native files should include all metadata associated with the Document. We are available to meet and confer regarding the technical specifications necessary for production.

DOCUMENTS TO BE PRODUCED

1. Correspondence to and from FDA related to Medichem's DMF and Nitrosamine Impurities.
2. Manufacturing development reports related to Medichem's DMF.
3. Analytical documents concerning impurities in the Varenicline Tartrate supplied by You to Zydus, including analytical method developments, and any analytical documents concerning the N-Nitroso-Varenicline and Diamide impurities.
4. Prior art concerning the manufacturing process for Varenicline Tartrate.
5. Documents concerning the launch of, or design review for, research and development of the manufacturing process for Varenicline Tartrate.
6. Documents sufficient to show any Medichem license, sale, or offer for sale of a Varenicline Tartrate product prior to March 11, 2022, including but not limited to product brochures or meeting presentations.

7. Documents sufficient to identify all lots of Varenicline Tartrate supplied by You to any third party, including the lot/batch number, the quantity of Varenicline Tartrate supplied, the date on which the Varenicline Tartrate was manufactured, the process used to manufacture the Varenicline Tartrate, and the date it was shipped to the third party.